

Application No. 09/710,181  
Amendment "G" dated May 27, 2004  
Reply to Office Action mailed March 31, 2004

### **REMARKS**

Claims 41-86 are pending, wherein claims 41, 59, 65, 72, 77 and 81 have been amended and new claim 86 has been added.

#### **I. REJECTION UNDER 35 U.S.C. § 102**

The Office Action rejects claims 41, 42, and 46-85 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,851,512<sup>1</sup>. In response, Applicants have amended each of the independent claims to specify that "the bleaching composition is formulated so that said potassium nitrate does not destabilize said bleaching agent". Support for this claim limitation is inherent in originally filed claim 18 of U.S. Application No. 09/694,516, filed October 23, 2000, now issued U.S. Patent No. 6,368,576, the disclosure of which was incorporated by reference when the present application was originally filed. Application, p. 2, lines 3-8. Claim 18 as originally filed, and now issued in U.S. Patent No. 6,368,576, recites "a stable, one-part composition". Inherent in the concept of "a stable, one-part composition" is that potassium nitrate contained therein does not destabilize the dental bleaching agent. Otherwise, the composition would not be "a stable, one-part composition", but would require two parts that are initially separated and are mixed together just prior to use.

The claims as now amended are neither anticipated by nor obvious over U.S. Patent No. 5,851,512 ("512 patent"). According to the '512 patent, potassium nitrate destabilizes peroxides such as hydrogen peroxide and carbamide peroxide such that peroxides can only be mixed with a potassium nitrate desensitizing composition just before treatment:

Finally, although most peroxides such as hydrogen peroxide and carbamide peroxide have been found to be unstable in the presence of potassium nitrate, it may be possible to add peroxide to the dental compositions of the present invention shortly before treatment in order to combine the bleaching and/or antiseptic action of the peroxide with the desensitization action of the potassium nitrate.

Col. 9, lines 36-41 (emphasis added). In view of this, Applicants submit that claims 41, 42 and 46-48 are neither anticipated by nor obvious over the '512 patent.

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<sup>1</sup> Whereas the Office Action states that the rejection "will not be maintained" the Examiner clarified by telephone that the rejection is being maintained.

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## **II. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS**

The Office Action rejects claims 43-45 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the '512 patent in view of U.S. Patent No. 5,985,249 ("249 patent"), col. 8, lines 48-62. In response, Applicants reiterate the fact that the '512 patent explicitly teaches that potassium nitrate destabilizes peroxide bleaching agents such as hydrogen peroxide and carbamide peroxide such that the two cannot be mixed together except shortly before use. The '249 patent teaches this exact same concept at col. 9, lines 46-51. Therefore, the '512 and '249 patents do not contain any claims directed to a composition in which the potassium nitrate does not destabilize the dental bleaching agent. In view of this, Applicants submit that claims 43-45 are therefore patentable and nonobvious over the claims of the '512 and '249 patents. Indeed, Applicants note that the initial obviousness-type double patenting rejection relative to the claims in U.S. Patent No. 6,309,625 over the '512 and '249 patents was removed during prosecution when it was pointed out that claims directed to a stable, one-part composition (*e.g.*, a composition in which the potassium nitrate does not destabilize the dental bleaching agent) are patentable over the claims of the '512 and '249 patents. Reconsideration and withdrawal of the rejection is respectfully requested.

The Office Action rejects claims 72-85 over U.S. Patent No. 6,368,576 ("576 patent") under the judicially-created doctrine of obviousness-type double patenting. The Office Action also rejects claims 41, 42, 46-55, 58-69 and 72-85 over U.S. Patent No. 6,309,625 ("625 patent") under the judicially-created doctrine of obviousness-type double patenting. Finally, the Office Action rejects claims 41-85 over U.S. Patent No. 6,306,370 ("370 patent") under the judicially-created doctrine of obviousness-type double patenting.

With respect to the '370 patent, Applicants point out that none of the claims contained therein are directed to "a stable, one-part dental bleaching composition" in which the potassium nitrate does not destabilize the dental bleaching agent. For this reason, Applicants did, in fact, file a terminal disclaimer during prosecution of the '370 patent relative to the '512 and '249 patents. This demonstrates the dissimilarity of the claims of the present application and those in the '370 patent. As a result, Applicants submit that the claims as now submitted are nonobvious over the claims of the '370 patent. Reconsideration and withdrawal of this rejection is respectfully requested.

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Applicants acknowledge that the '576 and '625 patents recite claims directed to "a stable, one-part dental bleaching composition". As such, but for Applicants' further arguments below, Applicants might have conceded that the claims as now amended ("subject claims") might arguably be obvious over claim 18 of the '576 patent and claims 1-26 of the '625 patent, since those claims specifically recite "a stable, one-part dental bleaching composition".

Nevertheless, Applicants submit that the claims are not obvious over the claims of any of the foregoing patents (collectively, the "cited art") because the subject claims are limited to a range of dental bleaching and desensitizing compositions that exhibit surprising and unexpected results relative to the broad range of compositions disclosed and claimed in the cited art. Applicants reincorporate by reference the arguments set forth in the previous amendment arguing why the claims are nonobvious over the claims of the cited references based on such surprising and unexpected results.

As set forth in the Office Action, the "Examiner agrees with Applicants' results" relating to the surprising and unexpected result that a relatively low concentration of desensitizing agent (0.5%) provides superior desensitization compared to bleaching compositions that contain a higher concentration of desensitizing agent (3% and above). Office Action, p. 2. The only disagreement with this evidence raised by the Examiner is that the "Examiner argues that the claims are far broader than the unexpected results proven by the Applicant". Office Action, p. 3. In response, Applicants point out that at least claims 46, 61, 65 and 81 are currently patentable over the prior art of record by the Examiner's own admission. In particular, the Examiner agrees that the test results show unexpected results when a concentration of 0.5% potassium nitrate is included. Therefore, it logically follows that claims 46, 61, 65 and 81, which require about 0.5% potassium nitrate, are currently patentable and nonobvious over the cited references by the Examiner's own admission.

The only remaining issue is whether the narrow range of about 0.05% to about 1% by weight potassium nitrate is sufficiently narrow and predictive of the surprising and unexpected result so as to also be nonobvious over the cited art. In support of Applicants' position that the test data adequately supports the narrow range of equivalent compositions recited in the claims, Applicants cite to MPEP § 716.02(d), which states that "nonobviousness of a genus or claimed range may be supported by data showing unexpected results of a species or narrower range under certain circumstances". Stated more fully, MPEP § 716.02(d) states that "the nonobviousness of

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a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the provative value thereof'. *In re Kollman*, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

In *In re Clemens*, the United States Court of Customs and Patent Appeals found that evidence showing that surprising and unexpected results were found at a temperature of 110°C and 130°C supported a broad claim that claimed any temperature above 100°C. The court also found that no unexpected results would be expected at temperatures of 60°C or below. While the court in *In re Clemens* would not allow claims that were broad enough to cover 60°C, it did not find the range of any temperature above 100°C to be "far broader than the unexpected results shown by Applicants" as now contended by the Examiner in the present application.

In the present application, the test results clearly show a trend that supports claiming a range of about 0.5% to about 1% potassium nitrate. As stated in the previous amendments, three different data points were tested: a first data point using 3% potassium nitrate, a second data point using 0.5% potassium nitrate, and a third data point using 0% potassium nitrate. The test data showed that the bleaching composition containing 0.5% potassium nitrate (the "prime data point") caused patients to experience far less of a wide range of different types of tooth and oral sensitivities. In contrast, using six times more potassium nitrate (*i.e.*, 3%), resulted in substantially higher tooth sensitivity and other types of oral sensitivity. Indeed, for some patients, including 3% potassium nitrate caused greater tooth and other oral sensitivities than when using no potassium nitrate. This study clearly demonstrated that, whereas potassium nitrate is generally believed to be a good tooth desensitizing agent at higher concentrations, even up to 50% potassium nitrate as set forth in the '625, '576 and '370 patents, the test data showed that when potassium nitrate is used in combination with a dental bleaching agent in order to bleach teeth, superior results were shown when only one-sixth of 3% (*i.e.*, 0.5%) potassium nitrate was used.

Since 3% potassium nitrate is the currently accepted commercial concentration used for desensitizing gels (as evidenced by a previously filed declaration), a clear trend is shown whereby less, not more, potassium nitrate results in reduced tooth and other oral sensitivities

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when potassium nitrate is not used alone but is combined with a dental bleaching agent. Indeed, less tooth and other oral sensitivity was experienced by some patients where 0% potassium nitrate was included compared to where 3% potassium nitrate was used, thereby showing that even very small concentrations of potassium nitrate, even as low as 0.05% (or even 0.01%), would be expected to result in less tooth and other oral sensitivities compared to 3% potassium nitrate or above, based on the comparative study. Thus, the surprising and unexpected results were not limited to a single data point (*i.e.*, the prime data point of 0.5% where the best results were found) but also at a second data point: using 0% potassium nitrate showed less sensitivity in some cases than using 3% potassium nitrate. This demonstrates a clear trend that using potassium nitrate at various concentrations less than 3% worked better than including 3% in reducing tooth and other oral sensitivities. According to *In re Clemens*, *In re Lindner*, *In re Kollman* and MPEP § 716.02(d), such results provide support and justification for claiming a narrowly tailored genus range based on the species data points because they show a "clear trend".

In further support of their contention that the surprising and unexpected results justify the claimed concentration range for potassium nitrate of about 0.05% to about 1%, Applicants will now compare the relationship between their data points and the claimed range with the relationship between the data points used in *In re Clemens* to support the claimed temperature range. This comparison will show that the range of "about 0.05% to about 1%" is as closely grouped around the data points of Applicants' study compared to the grouping of the temperature range allowed in *In re Clemens* with those data points. The lower temperature range endpoint allowed in *In re Clemens* (100°C) was 10°C less than the closest data point (110°C) where superior results were shown. The data point where poor results were expected in *In re Clemens* (60°C) was 40°C less than the lower temperature range endpoint. That means the court in *In re Clemens* allowed a range endpoint (100°C) that was four times closer to the relevant good data point (110°C) than to the bad data point (60°C) (*i.e.*, 40°C divided by 10°C equals 4).

In the present case, the claimed concentration range endpoint of about 1% is only about 0.5% greater than the prime data point (0.5%) shown in the comparative study, while being about 2% less than the bad data point (3%). That means the upper concentration range endpoint of about 1% is also, like what was allowed in *In re Clemens*, about four times closer to the relevant good data point (0.5%) than the bad data point (3%) (2% divided by 0.5% equals 4). The lower

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concentration range of 0.05% potassium nitrate is justified because it is much closer to both the prime data point (0.5%) and the second best data point (*i.e.*, 0%) than the worst data point (*i.e.*, 3%). This is consistent with *In re Clemens*, which allowed an open-ended upper temperature limit (anything above 100°C) that was far greater than the two data points of 110°C and 130°C because of the showing of a trend. In short, based on a comparison of the relevant data points in the present case with those that supported a broad range in *In re Clemens*, one must conclude that the relevant data points support the narrowly tailored concentration range of about 0.05% to about 1% potassium nitrate recited in independent claims 41, 59, 72 and 77.

For this reason, Applicants submit that claims 41-85 are nonobvious over the claims of the cited art because the test data show a clear trend and the claimed range is as closely related to the tested data points as the range allowed by the court in *In re Clemens*. Moreover, claims 46, 61, 65, and 81 are further nonobvious over the claims of the cited art because they each require about 0.5% potassium nitrate, which is essentially dead on with respect to the prime data point (0.5%), which the Examiner acknowledged was persuasive evidence of surprising and unexpected results.

Finally, Applicants have added new claim 86 in order to claim the originally claimed range of 0.01% to about 2% by weight of potassium nitrate, which Applicants also believe to be narrowly tailored relative to the test data points to justify a finding of nonobviousness relative to the claims of the cited art. In other words, Applicants believe claim 86 is sufficiently narrow as to be limited to bleaching compositions that exhibit improved desensitization compared to a composition that contains 3% or more potassium nitrate. Since one of skill in the art would never expect the use of less potassium nitrate to provide increased desensitization, but because the test data showed a clear trend that using less than 3% potassium nitrate caused less sensitivity than using 3% or more potassium nitrate, it follows that claiming less than about 2% potassium nitrate is unobvious over the claims of the cited art.

In further support of its position, Applicants refer to the various prophetic examples set forth in the application, each of which predicts surprising and unexpected results throughout the entire narrowly tailored range of about 0.01% to about 2% potassium nitrate. According to MPEP 2164.02, prophetic examples can be used to predict results based on actual results that were tested. Consistent with MPEP 2164.02, the current application includes, in addition to the comparative study that compares specific working examples using 0%, 0.5% and 3% potassium

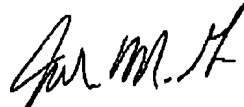
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nitrate, prophetic Examples 3-10. These examples state that including potassium nitrate in concentrations of 0.01%, 0.05%, 0.1%, 0.3%, 0.75%, 1%, 1.5% and 2% are expected to exhibit superior bleaching with less sensitivity compared to using no potassium nitrate. Page 29, lines 7-11. Based on the comparative study, it was reasonable for the inventors to also predict that including these amounts of potassium nitrate in a bleaching composition would lead to the surprising and expected result of causing less sensitivity than a bleaching composition that included 3% potassium nitrate. In short, Applicants submit that claim 86 is nonobvious over the claims of the cited art, none of which claim or suggest the narrowly tailored concentration range for potassium nitrate recited in claim 86 (or claims 41-85).

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or that may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 27<sup>th</sup> day of May 2004.

Respectfully submitted,



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